Exhibit C

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated, JOSEPH MACKEN, and COMMISSIONER LINDA) A. WATTERS, Plaintiffs, v. **ZENECA,** INC. and ASTRAZENECA PHARMACEUTICALS, L.P., Defendants.

Civ. No. 05-075-SLR (Lead Case)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2005 U.S. Dist. LEXIS 27444

November 8, 2005, Decided

CORE TERMS: labeling, advertisement, patients, misleading, omeprazole, heartburn, motion to dismiss, effective, dose, esophagitis, erosive, healing, negligent misrepresentation, class action, advertising, regulation, efficacy, symptom, placebo, pled, Lanham Act, unjust enrichment, federal law, new drug, impoverishment, nationwide, enrichment, actionable, deceptive, putative

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JUDGES: ROBINSON, Chief Judge.

OPINIONBY: Sue L Robinson

OPINION: MEMORANDUM OPINION

Dated: November 8, 2005
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On February 11, 2005, plaintiff Pennsylvania Employee Benefit Trust Fund filed a putative nationwide class action against AstraZeneca, Inc. and AstraZeneca Pharmaceuticals, L.P. (collectively called "defendants"). (D.I. 1) On April 5, 2005, Linda A. Watters n1 filed a putative nationwide class action against defendants. (Civ. No. 05-196-SLR, D.I. 1) On April 14, 2005, Joseph Macken filed a putative nationwide class action against defendants. (Civ. No. 05-220-SLR, D.I. 1) On May 27, 2005, Pennsylvania Employee Benefit Trust Fund, Linda A. Watters, Joseph Macken, AFSCME District Council 47 Health & Welfare Fund, Victoria Scofield, Janet McGrorty, Richard Tikkuri, Wisconsin Citizen Action, United Senior Action of Indiana and Carolina Fair Share (collectively called "plaintiffs") filed a consolidated class action complaint. (Civ. No. 05-75-SLR, D.I. 20, 27) n2 Before the court is defendants' motion to dismiss for failure to state a claim upon which relief can be granted. (D. **[*4]** I. 32) The court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a). (D.I. 1 at P 18)

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n1 More specifically, Ms. Watters filed suit in her capacity as Commissioner, Offices of Financial Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc.

n2 Unless otherwise noted, all references to "D.I." are to docket items in Civ. No. 05-75-SLR, the lead case in this consolidated action.

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II. BACKGROUND

According to the consolidated complaint (D.I. 20), the drug Prilosec is a proton-pump inhibitor ("PPI") used to treat heartburn and esophageal erosions. Id. By the year 2000, Prilosec, long advertised as the "purple pill", was the most widely prescribed drug in the world. Id. Before the patent on Prilosec expired, defendants received approval by the Food and Drug Administration ("FDA") for a new **[*5]** PPI, marketed as Nexium. (D.I. 20 at P 6) The FDA released the approved labeling for Nexium in February 2001. (D.I. 34, ex. 1) By 2003, sales of Nexium reached $ 3.3 billion. (D.I. 20 at P 13)

Plaintiffs allege that, once Prilosec could be sold as the generic drug omeprazole, defendants engaged in a massive advertising campaign to boost the sales of the more expensive prescription drug Nexium. In their advertisements, defendants "either implicitly or expressly represented" that Nexium was superior to Prilosec. In doing so, defendants "suppressed and/or omitted" information demonstrating that "Nexium . . . [is] not more effective at equivalent doses to the standard therapeutic dose of Prilosec." (D.I. 20 at 155(d)) (emphasis added) Plaintiffs assert that this misleading advertising campaign has resulted in "billions of dollars of unnecessary drug expenditures by third party payors" and that "hundreds of thousands of patients have taken Nexium and continue to do so when they should not." (D.I. 20 at PP 7, 9, 11, 86, 91, 98, 110, 155, 160) Plaintiffs contend that defendants' marketing strategy has violated the Delaware Consumer Fraud Act, 6 Del. C. § 2511 **[*6]** , et seq ("DCFA"), as well as the consumer protection statutes of the other 49 states. (D.I. 20 P 166) Plaintiffs also assert a claim for unjust enrichment and a claim of negligent misrepresentation. (D.I. 20 PP 173-78, 179-84)

III. STANDARD OF REVIEW

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiffs. See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiffs cannot demonstrate any set of facts that would entitle them to relief. See Conley v. Gibson, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957). The moving party has the burden of persuasion. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991). **[*7]**

IV. DISCUSSION

In order to prevail on their theory of liability, plaintiffs must demonstrate, first, that the Nexium advertisements "either implicitly or expressly" describe Nexium as superior to Prilosec and, second, that Nexium, in fact, is "not more effective at equivalent doses to the standard therapeutic dose of Prilosec." The question before the court instantly is whether it has jurisdiction to resolve these issues as pled. For

the reasons that follow, the court concludes that plaintiffs have not stated claims upon which relief can be granted.

A. Misleading Advertising Under the DCFA

With respect to the first issue, the DCFA provides that
the act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice.

6 Del. C. § 2513(a). The purpose of the DCFA is to **[*8]** "protect consumers and legitimate business enterprises from unfair or deceptive merchandising practices." 6 Del. C. § 2515. n3 Despite its broad purpose, however, the DCFA does not apply "to any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission." 6 Del. C. § 2513(b)(2). The Federal Trade Commission ("FTC") and the FDA share exclusive jurisdiction over regulation of drug marketing; the FDA is given primary authority to regulate prescription drugs. 36 Fed. Reg. 18,539 (1971) ("The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising."). The information included in the labeling of a new drug reflects a determination by the FDA that the information is not "false or misleading." 21 C.F.R. § 314.125(b)(6) (stating the FDA must deny a new drug application if it determines that "the proposed labeling is false or misleading in any particular"). By approving information to be included in the drug **[*9]** labeling, the FDA has determined that the information complies with its rules and regulations. Therefore, if the FDA labeling supports the statements made in advertising for an FDA-approved drug, the statements are not actionable under 6 Del. C. § 2513(b). American Home Products Corp. v. Johnson & Johnson, 672 F. Supp. 135 (S.D.N.Y. 1987) ("Moreover, AHP'S compliance with FDA labeling standards automatically puts it in compliance with FTC requirements as well, since the FTC has officially recognized that the FDA has primary jurisdiction over all matters relating to the labeling of [over the counter] drugs.") (internal citations omitted); Bober v. Glaxo Wellcome PLC, 246 F.3d 934, 942 (7th Cir. 2001) ("Recognizing the primacy of federal law in this field, the Illinois statute itself protects companies from liability if their actions are authorized by federal law."); see Solvay Pharmaceuticals, Inc. v. Ethex Corp., 2004 U.S. Dist. LEXIS 6003, 2004 WL 742033 (D. Minn. 2004) ("Where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA, plaintiffs cannot use the Lanham **[*10]** Act as a backdoor to private enforcement.") (citing Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990)).

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n3 Plaintiffs use statements made in defendants' 2000 Annual Report as evidence of false or misleading statements. The case law provides that the court "cannot ignore the clear language of the statute which restricts its application to deceptive practices 'in connection with the sale or advertisement' of merchandise."' Norman Gershman's

v. Mercedes-Benz, 558 A.2d 1066, 1074 (Del. Super. 1989). Plaintiffs have not alleged that any statements used in the Annual Report were used in the sale or advertisement of Nexium to consumers.

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Plaintiffs have characterized as misleading multiple statements found in the Nexium advertisements. These statements will be addressed in seriatim.

1. Nexium is a "new" drug. Defendants received FDA approval for a "new PPI". (D.I. 20 at P 6)

2. "The Purple Pill". The FDA-approved labeling describes **[*11]** the pill as "amethyst" in color. (D.I. 34, ex. 1 at 39)

3. "From the makers of Prilosec". Nexium is manufactured for AstraZeneca, as was Prilosec. (D.I. 34, ex. 1 at 40)

4. "Compared with Prilosec". Nexium was compared to Prilosec in the FDA approved labeling. (D.I. 34, ex. 1 at 13)

5. "Just one prescription Nexium a day gives may people complete resolution of heartburn symptoms". The FDA-approved labeling describes studies where "many" patients were symptom-free of heartburn with the use of Nexium. (D.I. 34, ex 1 at 14, 18) The labeling states:
Two multicenter, randomized, double-blind placebo-controlled studies were conducted in a total of 717 patients comparing four weeks of treatment with NEXIUM 20 mg or 40 mg once daily versus placebo for resolution of GERD symptoms. . . . The percentage of patients that were symptom-free of heartburn was significantly higher in the NEXIUM groups compared to placebo at all follow-up visits.

(D.I. 34, ex. 1 at 18) In addition, the labeling contains a chart of the Cumulative Percent with Sustained Resolution (defined as the cumulative proportion of patients who have reached the start of sustained resolution). **[*12]** After 14 days, the three studies resulted in 64.8%, 65.4%, and 67.6% (patients who reached the start of sustained resolution), respectively. After 28 days, the values were 74.2%, 73.9%, 75.1%. (D.I. 34, ex. 1 at 14) While the court need not define "many," it concludes these numbers are sufficient to support the statement made in the advertisement.

6. "Proven efficacy in short-term healing (4-8 weeks)". The FDA-approved labeling states that Nexium "is indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis." (D.I. 34, ex. 1 at 23) In addition, the labeling recommends 40 mg of Nexium once daily for 4 to 8 weeks for the healing of erosive esophagitis. (D.I. 34, ex. 1 at 37)

7. "Proven symptom control". The FDA-approved labeling describes studies where "the proportion of patients on Nexium who remained in remission and were free of heartburn and other GERD symptoms was well differentiated from placebo." (D.I. 34, ex. 1 at 18) Furthermore, the labeling concludes that, in a study done, "the percentage of patients that were symptom-free of heartburn was significantly higher

in the NEXIUM **[*13]** groups compared to placebo at all follow-up visits." (D.I. 34, ex. 1 at 18) . .

8. "Heal the damage". The FDA-approved labeling indicates Nexium is effective in the "healing and symptomatic resolution" of erosive esophagitis. (D.I. 34, ex. 1 at 14, 18, 23, 34)

9. "In GERD patients, power to control acid". The FDA-approved labeling includes a study done to determine the pH in patients with symptomatic gastroesophageal reflux disease (GERD). The data for Nexium 40 mg showed the pH remained above 4 for 16.8 hours. n4 (D.I. 34, ex. 1 at 7) With Nexium 20 mg, the pH remained above 4 for 12.7 hours.

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n4 A higher pH results in a less acidic enviornment.

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Plaintiffs take issue with this statement because, according to plaintiffs, the FDA reviewers do not believe that PPIs are effective for GERD patients in general. Nevertheless, Nexium was FDA-approved for treatment of GERD. (D.I. 34, ex. 1 at 37)

10. "Safety and tolerability similar to Prilosec". The FDA-approved labeling describes a study wherein **[*14]** the "safety in the treatment of healing erosive esophagitis" was conducted on patients taking Nexium 20 mg, Nexium 40 mg, omeprazole (Prilosec) 20 mg daily. "The most frequently occurring adverse events . . . in all three groups was headache (5.5, 5.0 and 3.8, respectively) and diarrhea (no difference among the three groups). Nausea, flatulence, abdominal pain, constipation, and dry mouth occurred at similar rates among patients taking Nexium or omeprazole." (D.I. 34, ex. 1 at 32)

Having reviewed all the advertising materials cited by plaintiffs, the court concludes that such materials are related to the safety and efficacy of Nexium, are consistent with the FDA-approved labeling and, therefore, are not actionable under the DCFA pursuant to 6 Del. C. § 2513(b)(2).

Alternatively, the court concludes that, even if the DCFA exception were held not to apply to the statements made in the Nexium advertisements, any statements made that comply with the FDA-approved labeling would not be actionable under a state consumer fraud act because they are preempted by federal law. The information included in the labeling of a new drug reflects a determination by the FDA **[*15]** that the information is not "false or misleading." 21 C.F.R. § 314.125(b)(6). See Cytyc Corp. v. Neuromedical Sys., Inc., 12 F.Supp.2d 296, 301 (S.D.N.Y. 1998) (granting a motion to dismiss because the challenged statements "comport substantively," even if not "precisely," with the FDA-approved labeling and can be considered "neither false nor misleading"); SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co., 1996 U.S. Dist. LEXIS 7257, 1996 WL 280810, *13 (S.D.N.Y. 1996) (concluding that in a Lanham Act case, the advertisements were "neither facially false nor misleading" because the

claims challenged were "based on the package labeling approved by the FDA"); American Home Products, 672 F.Supp. at 144 (holding that "compliance with FDA warning requirements" is a complete defense to Lanham Act and unfair competition claims). For this reason, the claims of violation of the deceptive practices and consumer fraud acts of the fifty states are dismissed. To the extent that any of these statutes do not have a similar exemption clause, the claims are preempted by the FDA's approved labeling.

B. [*16] Nexium's Efficacy

Plaintiffs claim that Nexium advertisements "either implicitly or expressly represent[]" that Nexium is superior to Prilosec "at equivalent doses." As a preliminary matter, in its review of the advertising materials of record, the court did not find any explicit statements that Nexium was "superior" to Prilosec. n5 Even if any of the advertisements were deemed to implicitly claim that Nexium is superior to Prilosec, the court concludes that such claims, if consistent with the FDA-approved labeling, related to the safety or efficacy of the drug and are excluded from liability under the DCFA. n6

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n5 The following statements mention Prilosec: **"We captured the essence of Prilosec . . . and created a new PPI . . . Introducing Nexium".** Nexium has been approved by the FDA as a "new PPI". Since both Prilosec and Nexium are PPIs, the court does not find the language "We captured the essence of Prilosec" as inconsistent with the FDA-approved labeling or as touting the superiority of Nexium over Prilosec. **"In erosive esophagitis sutdies compared with Prilosec".** As detailed above, Nexium was compared with Prilosec in studies. The advertisement does not comment on the results of the comparisons. Moreover, it is important to note that any comparisons made in the studies between omeprazole 20 mg (Prilosec) and Nexium 40 mg cannot be deemed misleading, as a 40 mg omeprazole (Prilosec) has not been approved by the FDA. **[*17]**

n6 Plaintiffs cite to an FDA reviewer who specifically looked at whether Nexium performed better than Prilosec. The court finds this is evidence that superiority is something the FDA considers in its labeling determinations. Therefore, claims of superiority do fall under the categories of safety and efficacy.

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Alternatively, in order to prevail on a claim that such an advertisement is false or misleading, plaintiffs would have the burden to prove the fact that the approved dosage of Nexium isnot superior to the approved dosage of omeprazole/Prilosec. The issue of whether one drug is more effective than another drug is clearly within the expertise of the FDA and should not be resolved in a court of law through the adversarial system. The court concludes, therefore, that plaintiffs have not stated a claim upon which relief can be granted by this court. See generally Sandoz, 902 F.2d at 230-32 (declining to decide whether a label is literally false when the FDA had yet to so determine).

C. Unjust Enrichment

"The elements of unjust enrichment are (1) an enrichment; (2) an **[*18]** impoverishment; (3) a relation between the enrichment and impoverishment; (4) the absence of justification; and (5) the absence of a remedy at law." Jackson Nat'l Life Ins. Co. v. Kennedy, 741 A.2d 377, 393 (Del. Ch. 1999). Plaintiffs have not pled a relationship between the alleged enrichment and the alleged impoverishment, as they have not specifically pled that they relied on the defendants' advertisements in purchasing Nexium. Furthermore, plaintiffs have not sufficiently pled an absence of justification by defendants regarding the advertisements. Indeed, the only foreseeable way to show an absence of justification is to show the misrepresentations are not true (i.e., that Nexium is not superior to Prilosec). As stated above, the court declines to entertain this argument.

D. Negligent Misrepresentation

For a claim of negligent misrepresentation, plaintiffs must allege: "(1) a pecuniary duty to provide accurate information, (2) the supplying of false information, (3) failure to exercise reasonable care in obtaining or communicating information, and (4) a pecuniary loss caused by justifiable reliance upon false information." HMG/Courtland Props., Inc. v. Gray, 749 A.2d 94, 1999 WL 504781, **[*19]** at *24 (Del. Ch. 1999) Plaintiffs have not alleged a justifiable reliance by each of the named plaintiffs in the suit and, thus, the claim for negligent misrepresentation is dismissed.

V. CONCLUSION

For the reasons stated herein, defendants' motion to dismiss is granted. An appropriate order shall issue.

ORDER

At Wilmington this 8th day of November, 2005, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that defendants' motion to dismiss (D.I. 32) is granted.

United States District Judge